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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

7590 05/31/2006  
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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/559,401	YUYAMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Luke Gilligan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Amendment***

1. In the amendment filed 3/15/06, the following has occurred: no claims have been added, amended, nor canceled. Now, claims 19-37 are presented for examination.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 19-32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Teeple Jr., U.S. Patent No. 5,925,014.
4. Claims 19-32 and 34 are unamended. Therefore, claims 19-32 and 34 are rejected for the same reasons given in the previous Office Action, mailed 12/15/05, incorporated herein by reference.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teeple Jr., U.S. Patent No. 5,925,014 in view of Merki et al., U.S. Patent No. 5,002,055.

7. Claim 33 is unamended. Therefore, claims 19-32 and 34 are rejected for the same reasons given in the previous Office Action, mailed 12/15/05, incorporated herein by reference.

8. Claim 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teeple Jr., U.S. Patent No. 5,925,014 in view of Leissing et al., U.S. Patent No. 5,281,396.

9. Claims 35-37 are unamended. Therefore, claims 19-32 and 34 are rejected for the same reasons given in the previous Office Action, mailed 12/15/05, incorporated herein by reference.

### ***Response to Arguments***

10. In the remarks filed 3/15/06, Applicants argue in substance that (1) Teeple does not teach each of the 4 elements of claim 19; (2) Merki does not teach determining a proper mixing order of a plurality of injections which are prescribed to a patient based on pH-value data of the injections; (3) Leissing does not teach deciding and displaying a proper mixing order of a plurality of injections; (4) Leising does not teach an operation unit operable to record a composition alteration, and a recorder operable to record the composition alteration.

11. In response to Applicants' argument (1), the Examiner will address Applicants' remarks with respect to each element of claim 19 in order:

With respect to the first element of claim 19, the Examiner respectfully disagrees with Applicants assertion that the input means is merely for inputting data corresponding to a patient's weight. Although patient weight is input into the system, clearly this is not the only data that is inputted. For example, Teeple clearly indicates that upon the input

by the user of the requisite variables (i.e. drugs to be administered), the device determines the proper dosage, infusion bag mixing, and labeling (see column 9, lines 4-17). Therefore, it is respectfully submitted that Teeple clearly teaches acquiring injection prescription data that specifies patient injections.

With respect to the second element of claim 19, the Examiner respectfully disagrees with Applicants' assertion that Teeple only determines a concentration of a drug to be infused to a patient. The Examiner agrees that determining a concentration by determining a proper level of diluent is a feature of the system of Teeple. However, Teeple clearly states, repeatedly throughout the disclosure, that a proper mix of drugs or drug concentrates is determined. For example, Teeple includes "means for displaying the required concentration and/or preparing the final mixed bad of drugs and dilute to be administered" (see column 3, lines 54-56, emphasis added). In fact it is a stated objective of Teeple to overcome the prior art difficulties for anesthesiologists to administer a combination of drugs (see column 1, lines 22-28). Therefore, the Examiner respectfully maintains that Teeple teaches this element of the claim.

With respect to the third element of claim 19, as noted above, the Examiner respectfully disagrees with Applicants' assertion that Teeple merely teaches determining, and therefore displaying, a required concentration. Since Teeple teaches that the decided mix of drug, diluent, and dosage rate is printed out by a label maker (see column 9, lines 21-24), the Examiner respectfully submits that Teeple teaches this element of the claim for the reasons given above with respect to the second element.

With respect to the fourth element, Applicants again restate that Teeple teaches a final mixing bad of drugs and dilute but not properly combining the drugs. The Examiner, therefore incorporates the response with respect to the second element

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herein. In addition, the Examiner emphasizes Teeples teaching of a “means for mixing dilutant and drug concentrate(s) into a final mixed bag ready for administration” (see column 3, lines 57-58, emphasis added).

12. In response to Applicants’ argument (2), it is respectfully submitted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case the Examiner has only relied upon the teachings of Merki for determining a mixing order of injections in accordance with pH-values. Although Merki makes the determination during the infusion, it is respectfully submitted that it would have been obvious one of ordinary skill in the art to combine the teaching of making this determination with the system of Teeple which, as described above, teaches determining a proper mixing order of injections prescribed to a patient.

13. In response to Applicants’ argument (3), again, it is respectfully submitted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Since the Examiner has not relied upon the teachings of Leissing for this feature, it is respectfully submitted that this argument is not persuasive in view of the current grounds of rejection.

14. In response to Applicants’ argument (4), although Applicants’ remarks do not address this limitation differs from the portions of Leissing cited by the Examiner, it is respectfully submitted that Leissing determines a plurality of types of composition alterations such as turbidity (see column 6, lines 16-20). Furthermore, this information is recorded in a database (see column 6, lines 60-68).

***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/26/06

  
C. LUKE GILLIGAN  
PATENT EXAMINER